UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/814,982	03/30/2004	Valery M. Dubin	21058/0206743-US0	8631	
75172 Client 21058	7590 05/20/200	9	EXAMINER		
c/o DARBY &	DARBY P.C.		JUNG, UNSU		
P.O. BOX 770 CHURCH STREET STATION			ART UNIT	PAPER NUMBER	
NEW YORK, N	NEW YORK, NY 10008-0770			1641	
			MAIL DATE	DELIVERY MODE	
			05/20/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/814,982	DUBIN ET AL.				
Office Action Summary	Examiner	Art Unit				
	UNSU JUNG	1641				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 17 Fe	ebruary 2009					
, <u> </u>	action is non-final.					
<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-5,7-16,19-21 and 54-59</u> is/are pendi	ing in the application.					
4a) Of the above claim(s) <u>5</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-4,7-16,19-21 and 54-59</u> is/are rejected.						
7) Claim(s) is/are objected to.						
•						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>03 August 2007</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) X Notice of References Cited (PTO-892)	4) ☐ Interview Summary	(PTO-413)				
2) Notice of Traftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ite				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:						
Paper No(s)/Mail Date 6) L Other:						

DETAILED ACTION

Response to Amendment

1. Applicant's amendments in the reply filed on February 17, 2009 have been acknowledged and entered. The reply included cancellation of claims 41-53 and addition of new claims 56-59.

Status of Claims

2. Claims 1-5, 7-16, 19-21, and 54-59 are pending, claim 5 has been previously withdrawn from consideration, and claims 1-4, 7-16, 19-21, and 54-59 are currently under consideration for patentability under 37 CFR 1.104.

Priority

3. The instant application has a filing date of March 30, 2004 and does not claim for the benefit of a prior-filed application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1641

5. Claims 1-4, 7-16, 19-21, 54, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "similar" in claim s 1 and 14 and all dependent claims thereof is a relative term which renders the claim indefinite. The term "similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the limitation of "the electrodes having structures and/or charge distributions similar to the target molecule" has been rendered indefinite as it is unclear what degree of similarity is required for the electrode structures and/or charge distributions and the target molecule. For the purpose of examination, the limitation has been interpreted in light of the specification, which discloses that the structure/distribution approach can be based on DNA molecular recognition ability (p9, paragraph [0037]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1641

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 9. The following prior art rejections may include modified portions, which have been bolded, due to addition of new claims 56-59 in the reply filed on February 17, 2009.
- 10. Claims 1-4, 7-12, 19-21, 54, **56, and 57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et

al. (WO 2004/001404 A1, published on December 31,2003 and filed on June 19, 2003), Chazalviel et al. (*Applied Spectroscopy*, 1993, Vol. 47, pp1411-1416), and Yoshida et al. (JP 07-184883 A, July 25, 1995).

Li teaches an apparatus comprising a condensed array addressed device (see entire document, particularly p8) including a plurality of addressable cells (p8, Detailed Description of the Invention, 1st paragraph), each of the plurality of addressable cells including at least two electrodes (reference elements 1 and 5 in Fig. 2; reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5); and a spectroscope optically coupled to the condensed array addressed device (p34, last paragraph and p35). The apparatus of Li further includes microfluidic trench for containing one or more target molecules (reference element 7 in Fig.'s 1 and 3 and p39, 1st paragraph).

With respect to the limitation of "electrodes having structures and/or charge distributions similar to the target molecule" as recited in claim 1, Li teaches that electrodes further comprises probe molecules that specifically bind to interact with target molecules (p4, last paragraph-p5, 1st paragraph) and that the probe molecules can include nucleotide sequence, which hybridizes with a target DNA (molecular recognition, p12, 2nd paragraph).

With respect to claims 8 and 9, Li teaches that the plurality of addressable cells includes an individually addressable cell, which includes a first individually addressable electrode and a second individually addressable electrode (p8, Detailed Description of the Invention, 1st paragraph).

Art Unit: 1641

With respect to claims 10-12, Li teaches that spacing between the electrodes is less than 1 µm (p17, 5th paragraph). Li further teaches that cross-dimensions of microchannels, in which the electrodes are located, are in the order of 0.1 to 500 µm (p19, 1st paragraph and Fig. 9C). Therefore, one of ordinary skill in the art would recognize that the electrodes located within the microchannels would have less than 100 nm in size since the electrodes contained within the microchannels would necessarily have to be less than the cross-dimensions of microchannels.

With respect to claim 19, Li teaches an apparatus, further comprising a microfluidic channel coupled to at least one of the addressable cells (p18, last paragraph and p19, 1st paragraph).

With respect to claims 20 and 21, Li teaches an apparatus, further comprising selective membranes (porous polymeric pads), which includes chemically and biologically selective membranes (p5, last paragraph).

With respect to claim 54, Li teaches a target molecule comprising DNA (p12, 2nd paragraph).

With respect to claim 56, Li teaches that the electrodes are solid state electrodes (p3, Summary of the Invention, 3rd paragraph).

With respect to the limitation of "the structures and/or charge distributions similar to the target molecule is based on DNA molecular recognition ability" as recited in claim 57, Li teaches that electrodes further comprises probe molecules that specifically bind to interact with target molecules (p4, last paragraph-p5, 1st

Application/Control Number: 10/814,982

Art Unit: 1641

paragraph) and that the probe molecules can include nucleotide sequence, which hybridizes with a target DNA (molecular recognition, p12, 2nd paragraph).

Page 7

Li further teaches that a variety of detection methods can be used with the condensed array addressed device including optical detection methods capable of detecting spectral changes upon changes in redox state including fluorescence, phosphorescence, luminescence, chemiluminescence, electrochemiluminescence, and refractive index detection methods. However, Li does not specifically teach that two different detection means, electrochemical and optical (spectroscope), are coupled to the array device. Li further does not specifically teach an apparatus further comprising a waveguide, which includes a total internal reflection prism, wherein the spectroscope is optically coupled to the total internal reflection prism.

DeNuzzio et al. teaches microfabricated sensors with multiple working electrodes coupled to both optical and electrochemical detection means allowing the combination of the multiplexed electrochemical detection with optical detection in a single planar microcell (see entire document, particularly Abstract and p5, paragraph [0014]). The combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously (p9, paragraph 0030]).

With respect to claims 1-3, Chazalviel et al. teaches Fourier Transform (FT)-infrared (IR) spectroscopy, which is a well-known spectral detection method at the electrochemical interfaces (entire document, particularly p1416, *Conclusion*). The advantages of FT-IR spectroscopy are well known (p1416, *Conclusion*). The

advantages include good sensitivity and ability to smoothly extract varying contributions due to electronic absorptions and to obtain spectra as complex quantities, which is of

Page 8

considerable help in the identification of the vibration signals and in their ascription to

one or the other of the many possible electrochemical processes (p 1416, Conclusion).

With respect to claims 1 and 7, Yoshida et al. teaches an optical system comprising FT-IR spectroscopy and an ATR (attenuated total internal reflection) prism, which provides infrared rays to infrared analysis equipment such as FT-IR spectroscopy (see entire translated document, particularly Abstract and paragraph [0005]).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ combination of both optical and electrochemical detectors of Li as taught by DeNuzzio et al. in order to allow a combination of multiplexed electrochemical detection with optical detection in a single device.

The advantage of allowing a combination of multiplexed electrochemical detection with optical detection in a single device provides the motivation to combine teachings of Li and DeNuzzio et al. since the combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously.

Further, one of ordinary skill in the art would have had a reasonable expectation of success in employing the combination of both optical and electrochemical detectors in the device of Li since DeNuzzio et al. teaches that simultaneous detection of both

optical and electrochemical signals is possible with the combination of the multiplexed electrochemical detection with optical detection.

Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the FT-IR spectroscopy of Chazalviel et al. in the apparatus of Li in order to provide a spectral detection device at the electrochemical interfaces of the condensed array addressed device of Li for optical detection of biomoleclular interactions.

The advantage of employing a sensitive detection device, which facilitates spectra information in complex quantities, provides the motivation to employ the FT-IR spectroscopy of Chazalviel et al. in the apparatus of Li with a reasonable expectation of success since the FT-IR spectroscopy is capable of smoothly extracting varying contributions due to electronic absorptions and obtaining spectra in complex quantities permitting identification of the vibration signals.

In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select FT-IR spectroscopy as a detection system, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. Because the claimed apparatus is known in the prior art and has been disclosed as being used with a spectroscope in general, the selection of a specific type of a spectroscope in itself does not present a novel feature of the claimed invention. Since one of ordinary skill in the art at the time of the invention would recognize that a plurality of different types of detection system can be used in the

Art Unit: 1641

apparatus of Li for detection of biomolecular interactions based on the same principle of detecting electrochemical species, it would have been obvious to employ a FT-IR spectroscopy as a detection system in the instant claims.

Moreover, it would have been *prima facie* obvious to further include a total internal reflection prism (waveguide), which is optically coupled to the FT-IR spectroscope as taught by Yoshida et al. in the apparatus of Li in view of Chazalviel et al. as it is generally known to use total internal reflection prisms in order to provide infrared rays to FT-IR spectroscope. Since the FT-IR spectroscopy of Yoshida et al. can be coupled to the electrochemical interfaces of the condensed array addressed device of Li as set forth above and the electrochemical interfaces of Li includes a microfluidic trench containing addressable cells having at least two electrodes, the combined teachings of Li, DeNuzzio et al., Chazalviel et al. and Yoshida et al. meet the amended feature of "the waveguide total internal reflection prism is coupled to the microfluidic trench."

With respect to claim 4, the limitation of "the infrared spectroscope is electromodulated by applying potential between the at least two electrodes in at least one of the plurality of cells" is a recitation of the intended use of the claimed invention and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The apparatus of Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. meets all the structural limitation of claim 4 and would therefore be capable of performing the

intended use limitation above. Further, Li teaches that a potential is applied between the two electrodes in the plurality of cells (p34, 4m paragraph).

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Chazalviel et al. (Applied Spectroscopy, 1993, Vol. 47, pp1411-1416), and Yoshida et al. (JP 07-184883 A, July 25, 1995) as applied to claims 1 and 10 above, and further in view of Dai et al. (U.S. Patent No. 6.528,020, Mar. 4, 2003).

Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. teaches an apparatus comprising a condensed-array addressed device and an optically coupled spectroscope as set forth above. Li further teaches that each of the pair of electrodes includes carbon nanotubes (p23, 3rd paragraph). However, Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. does not specifically teach that each of the pair of electrodes includes single-walled carbon nanotubes or silicon nanowires.

Dai et al. teaches chemical/biological sensors comprising electrochemical nanotube devices, which demonstrate significant and robust response and more significantly tunable selectivity to chemical or biological species in their environments (see entire document). The nanotube is generally single-walled carbon nanotube or silicon nanotubes (nanowires, column 2, lines 21-27 and column 4, lines 17-22).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to specifically employ single-walled carbon nanotubes or

Art Unit: 1641

silicon nanowires of Dai et al. as the nanotubes associated with the pair of electrodes of Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al., as it is well known that the electrochemical nanotube devices demonstrate significant and robust response and more significantly tunable selectivity to chemical or biological species in their environments.

In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select single-walled carbon nanotubes or silicon nanowires as a layer covering the electrodes of the condensed array addressed device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. Because the claimed apparatus is known in the prior art and has been disclosed as being capable of being used with carbon nanotubes in general, the selection of a specific type of a nanotube/nanowire in itself does not present a novel feature of the claimed invention. Since one of ordinary skill in the art at the time of the invention would recognize that a plurality of different types of nanotubes/nanowires can be used in the apparatus of Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. for detection of biomolecular interactions based on the same principle of detecting electrochemical species, it would have been obvious to employ a single-walled carbon nanotubes or silicon nanowires in the instant claims.

12. Claims 14-16, 55, and **58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO

2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Ito (U.S. Patent No. 5,384,028, Jan. 24, 1995), and Girault et al. (U.S. Patent No. 5,512,489, Apr. 30, 1996).

Li teaches an apparatus comprising a condensed array addressed device (see entire document, particularly p8) including a plurality of addressable cells (p8, Detailed Description of the Invention, 1st paragraph), each of the plurality of addressable cells including at least two electrodes (reference elements 1 and 5 in Fig. 2; reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5); and a spectroscope optically coupled to the condensed array addressed device (p34, last paragraph and p35). The apparatus of Li further includes microfluidic trench for containing one or more target molecules (reference element 7 in Fig.'s 1 and 3 and p39, 1st paragraph).

With respect to claim 14, Li teaches that the plurality of addressable cells define a plurality of sensor elements configured as an array, wherein each of the sensor elements is functionalized to interact with one or more target molecules (p23, 2nd -7th paragraphs); and further comprising control circuitry coupled to the sensor elements, wherein the control circuitry is configured to detect interactions of the sensors with the target molecules (p24, 4th paragraph). The addressable cells of Li contain a first electrode and a second electrode (reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5), wherein the first tip of the first electrode and the second tip of the second electrode are located in the microfluidic trench (Fig.'s 1 and 3). The first electrode and the second electrode are each coupled to first and second traces

Art Unit: 1641

(input and outputs) via first and second conductive plugs, respectively (Fig. 5 and p17, 2nd paragraph). With respect to the limitation of "electrodes having structures and/or charge distributions similar to the target molecule" as recited in claim 14, Li teaches that electrodes further comprises probe molecules that specifically bind to interact with target molecules (p4, last paragraph-p5, 1st paragraph) and that the probe molecules can include nucleotide sequence, which hybridizes with a target DNA (molecular recognition, p12, 2nd paragraph).

With respect to claims 15 and 16, Li teaches the plurality of sensor elements configured as a two-dimensional high-density array (p39, 3rd paragraph), which are addressable by corresponding rows and columns.

With respect to claim 55, Li teaches a target molecule comprising DNA (p12, 2nd paragraph).

With respect to claim 58, Li teaches a signal amplifier (p37, 3rd paragraph).

Li further teaches that a variety of detection methods can be used with the condensed array addressed device including optical detection methods capable of detecting spectral changes upon changes in redox state including fluorescence, phosphorescence, luminescence, chemiluminescence, electrochemiluminescence, and refractive index detection methods. However, Li does not specifically teach that two different detection means, electrochemical and optical (spectroscope) detectors are coupled to the array device. Li further teaches that other electronic components can be added to the apparatus including circuitry that allows signal processing (p24, 4th paragraph). However, Li is silent on an apparatus further comprising memory coupled

to the control plurality of sensor elements in the memory. The apparatus of Li includes an array addressed device in a microarray format as set forth above. Although the microarray format of Li would allow the apparatus of Li to be hand-held, Li fails to explicitly teach that the apparatus is a hand-held device.

DeNuzzio et al. teaches microfabricated sensors with multiple working electrodes coupled to both optical and electrochemical detection means allowing the combination of the multiplexed electrochemical detection with optical detection in a single planar microcell (see entire document, particularly Abstract and p5, paragraph [0014]). The combination of various electrochemical, photometric, and other measurements results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously (p9, paragraph 0030]).

Ito teaches that a memory device for storing data can be provided with a biosensor for storing data (see entire document, particularly Abstract). The data include a fabrication date for the biosensor, a lot number, an effective period of the biosensor, biosensor characteristics, measured date, measuring time, and measured results (Abstract).

Girault et al. teaches a device which need not be laboratory bound (see entire document, particularly column 3, lines 52-57). The device is a multi-heavy metal ion detector directed essentially at in-the-field measurement which may be used as a portable hand-held device or form part of a remote sensing network (column 3, lines 52-57). The device of Girault et al. electroanalysis can be easily adapted to enzyme chemistry or/and immunochemistry for use as a biosensor (column 7, lines 12-20).

Art Unit: 1641

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ a combination of both optical and electrochemical detectors of Li as taught by DeNuzzio et al. in order to allow a combination of multiplexed electrochemical detection with optical detection in a single device.

The advantage of allowing a combination of multiplexed electrochemical detection with optical detection in a single device provides the motivation to combine teachings of Li and DeNuzzio et al. since the combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously.

Further, one of ordinary skill in the art would have had a reasonable expectation of success in employing the combination of both optical and electrochemical detectors in the device of Li since DeNuzzio et al. teaches that simultaneous detection of both optical and electrochemical signals is possible with the combination of the multiplexed electrochemical detection with optical detection.

In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include the memory device of Ito, which is configured to store data, coupled to the control circuit of Li in view of DeNuzzio et al. in order to store data associated with plurality of sensor elements.

The advantage of storing data, which may include a fabrication date for the biosensor, a lot number, an effective period of the biosensor, the biosensor

Art Unit: 1641

characteristics, measured date, the measuring time, and the measured results, provides the motivation to include the memory device of Ito coupled to the control circuit of Li in view of DeNuzzio et al. with a reasonable expectation of success.

Although Li in view of DeNuzzio et al. and Ito fails to explicitly teach that the apparatus is a hand-held device, one of ordinary skill in the art at the time of the invention would have been motivated to construct the apparatus of Li in view of DeNuzzio et al. and Ito in a hand-held device format with a reasonable expectation of success since Girault et al. teaches that electrode array biosensor devices can be used as a portable hand-held device, which need not be laboratory bound and has the advantage of allowing in-the-field measurements.

13. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Ito (U.S. Patent No. 5,384,028, Jan. 24, 1995), and Girault et al. (U.S. Patent No. 5,512,489, Apr. 30, 1996) as applied to claim 14 above, and further in view of Torch (U.S. Patent No. 6,163,281, Dec. 19, 2000) and Wohlstadter et al. (U.S. Patent No. 6,090,545, July 18, 2000).

Li in view of DeNuzzio et al., Ito, and Girault et al. teaches an apparatus comprising a condensed-array addressed device and an optically coupled spectroscope as set forth above. However, Li in view of DeNuzzio et al., Ito, and Girault et al. fails to teach an apparatus further comprising a video display.

Art Unit: 1641

Torch teaches that data may be displayed graphically on a computer of video screen or other electronic display device (see entire document, particularly column 8, lines 13-29).

Wohlstadter et al. teaches that signal processing means such as a digital computer can be used for transferring, recording, analyzing and/or displaying the results of assays (see entire document, particularly column 42, lines 59-63).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ a computer of Torch with a video screen/display in the apparatus of Li in view of DeNuzzio et al., Ito, and Girault et al. in order to use the computer for transferring, recording, analyzing and/or displaying the results of assays. The advantage of allowing the transfer, recording, analysis and/or displaying of the assay results provides the motivation to combine teachings of Li in view of DeNuzzio et al., Ito, and Girault et al. and Torch with a reasonable expectation of success since Wohlstadter et al. teaches that signal processing means such as a digital computer can be used for transferring, recording, analyzing and/or displaying the results of assays.

Response to Arguments

14. Rejection of claims 1-4, 7-16, 19-21, 54, and 55 under 35 U.S.C. 112, second paragraph

Applicant's argument that the claims 1-4, 7-16, 19-21, 54, and 55 are not indefinite when the claims are interpreted in light of the specification has been fully considered but is not found persuasive. Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, the limitation of "the electrodes having structures and/or charge distributions similar to the target molecule" has been rendered indefinite as it is unclear what degree of similarity is required for the electrode structures and/or charge distributions and the target molecule as set forth in the previous Office Action dated November 14, 2008 (see item 4).

In view of the foregoing response to arguments, the rejection of claims 1-4, 7-16, 19-21, 54, and 55 under 35 U.S.C. 112, second paragraph has been maintained.

15. Rejection of claims 1-4, 7-12, 19-21, 54, 56, and 57 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al.

Applicant's arguments filed on February 17, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's argument that the Examiner merely hypothesized that the FT-IR spectroscopy of Yoshida et al. can be coupled to the electrochemical interfaces of the condensed array addressed devices of Li but not explained how or why one of ordinary skill in the art at the time of the invention would have modified the apparatus of Li with Yoshida to couple the waveguide total internal reflection prism to the microfluidic trench as recited in claim has been fully considered but is not found persuasive essentially for the reasons of record.

Art Unit: 1641

Regarding to applicant's argument of how one of ordinary skill in the art at the time of the invention would have modified the apparatus of Li with Yoshida to couple the waveguide total internal reflection prism to the microfluidic trench as recited in claim, Chazalviel et al. teaches Fourier Transform (FT)-infrared (IR) spectroscopy, which is a well-known spectral detection method at the electrochemical interfaces (entire document, particularly p1416, *Conclusion*) as set forth in the previous Office Action dated November 14, 2008 (see item 9). Therefore, Chazalviel et al. does teach how to apply FT-IR spectroscopy to electrochemical interfaces.

In response to applicant's argument that there is no suggestion/reason to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As set forth in the previous Office Action dated November 14, 2008 (see item 9), Yoshida et al. teaches an optical system comprising FT-IR spectroscopy and an ATR (attenuated total internal reflection) prism, which provides infrared rays to infrared analysis equipment such as FT-IR spectroscopy (see entire translated document, particularly Abstract and paragraph [0005]). Given the teachings of Li and Chazalviel et al., it would have been *prima facie* obvious to further include a total internal reflection prism (waveguide), which is optically coupled to the FT-IR spectroscope as taught by Yoshida et al. in the

apparatus of Li in view of Chazalviel et al. as it is generally known to use total internal reflection prisms in order to provide infrared rays to FT-IR spectroscope. Since the FT-IR spectroscopy of Yoshida et al. can be coupled to the electrochemical interfaces of the condensed array addressed device of Li as set forth above and the electrochemical interfaces of Li includes a microfluidic trench containing addressable cells having at least two electrodes, the combined teachings of Li, DeNuzzio et al., Chazalviel et al. and Yoshida et al. meet the feature of "the waveguide total internal reflection prism is coupled to the microfluidic trench." The advantage of employing a sensitive detection device, which facilitates spectra information in complex quantities, provides the motivation to combine teachings of Li, Chazalviel et al., and Yoshida et al. with a reasonable expectation of success.

In view of the foregoing response to arguments, the rejection of claims 1-4, 7-12, 19-21, 54, 56, and 57 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. has been maintained.

16. Rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over DeNuzzio et al., Chazalviel et al., and Yoshida et al., and further in view of Dai et al.

Applicant's arguments filed on February 17, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed above.

In view of the foregoing response to arguments, the rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al., and further in view of Dai et al. has been maintained.

Art Unit: 1641

17. Rejection of claim 14-16, 55, and 58 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio et al., Ito, and Girault et al.

Applicant's arguments filed on February 17, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's argument regarding the limitation of "wherein a first tip of the first electrode is located in the microfluidic trench and electronically coupled to a first trace via a first conductive plug and a second tip of the second electrode is located in the microfluidic trench and electronically coupled to a second trace via a second conductive plug" has been fully considered but is not found persuasive essentially for the reasons of record. Specifically applicant's assertion that Li does not teach that the first electrode and the second electrode are each coupled to first and second traces via first and second conductive plugs, respectively, has been fully considered but is not found persuasive essentially for the reasons of record. As set forth in the previous Office Action dated November 14, 2008 (see item 9), Li teaches that the plurality of addressable cells define a plurality of sensor elements configured as an array, wherein each of the sensor elements is functionalized to interact with one or more target molecules (p23, 2nd -7th paragraphs); and further comprising control circuitry coupled to the sensor elements, wherein the control circuitry is configured to detect interactions of the sensors with the target molecules (p24, 4th paragraph). The addressable cells of Li contain a first electrode and a second electrode (reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5), wherein the first tip of the first

Art Unit: 1641

electrode and the second tip of the second electrode are located in the microfluidic trench (Fig.'s 1 and 3). The first electrode and the second electrode are each coupled to first and second traces (input and outputs) via first and second conductive plugs (leads), respectively (Fig. 5 and p17, 2nd paragraph). According to the current specification, the term "conductive plugs" is not specifically defined. The specification discloses that the plugs comprise conductive materials such as metal (p14, paragraphs [0051] and [0052]). Therefore, the leads of Li, reads on the "conductive plugs" of the claimed invention as Li teaches that the leas are conductive paths generally made of gold or copper or other materials suitable for formulation of electrodes (p17, 3rd paragraph).

In view of the foregoing response to arguments, the rejection of claims 14-16, 55, and 58 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio et al., Chazalviel et al., Ito, and Girault et al. has been maintained.

18. Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

- 19. No claim is allowed.
- 20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1641

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/ Unsu Jung Primary Examiner Art Unit 1641